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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,308	06/06/2001	Takeshi Fujita	381NT/42535D2	8142

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/30/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,308

Applicant(s)

FUJITA ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/552,496.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5 and 6</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Preliminary Amendment

2. Preliminary Amendments filed on June 6, 2001 have been enter in Paper Nos: 2-4. Since claims 47-49, 60, and 62 have been canceled, pending claims are claims 50-59.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 50-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 51-59 are dependent on claim 50.

5. Claim 50 is rejected as vague and indefinite in view of the phrase "the base paring nucleotides formed by a conformation of the sample single-stranded DNA fragment in the sample solution" because it is unclear how the base paring nucleotides are formed in the sample single-stranded DNA fragment by its conformation. For example, does this phrase mean that the

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sample single-stranded DNA fragment in the sample solution forms the base pairing nucleotides by change its conformation or the phrase mean something else? Please clarify.

6. Claim 50 is rejected as vague and indefinite because it is unclear how “any kind of denaturation of single stranded DNA fragment” is correlated with “a melting curve”. It was known that only heat denaturation of single stranded DNA fragment generates a melting curve. Please clarify.

7. Claim 50 is rejected as vague and indefinite in view of the phrase “for analyzing for a DNA polymorphism including a single-base substitution in the sample single-stranded DNA fragment” because it is unclear what it intended. For example, since “including” is equivalent to the phrase “such as”, it is unclear whether the claim is limited to a single-base polymorphism or not? Please clarify. Note that the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

8. Claim 51 is rejected as vague and indefinite in view of phrase “determining that the data set of the known melting curve with a least statistical error or the linear combination of the data sets with a least statistical error represents the sequence information of the sample single-stranded DNA fragment” because it is unclear what it intended. For example, how the data set of the known melting curve with a least statistical error or the linear combination of the data sets with a least statistical error is correlated with the sequence information of the sample single-stranded DNA fragment. It was known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Does the

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phrase “the known melting curve with a least statistical error” mean the known melting curve with least statistical error? Please clarify.

9. Claim 52 is rejected as vague and indefinite in view of phrase “selecting one curve data with a least statistical error” because it is unclear what it intended. Does this phrase mean selecting one curve data with least statistical error or this phrase mean something else? Please clarify.

10. Claim 52 is rejected as vague and indefinite in view of phrase “representing a given number of the curve data sets in the increasing order of the least statistical error as the sequence information of the measured sample single-stranded DNA fragment” because it is unclear how a given number of the melting curve data sets in the increasing order of the least statistical error is correlated with the sequence information of the measured sample single-stranded DNA fragment. It was known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

11. Claim 52 is rejected as vague and indefinite in view of phrase “determining that a known melting curve data set with a least statistical error is defined as the sequence information of the sample single-stranded DNA fragment” because it is unclear how a known melting curve data set with a least statistical error can be defined as the sequence information of the sample single-stranded DNA fragment. It was known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

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12. Claim 59 is rejected as vague and indefinite in view of phrase “a linear combination of the known melting curve data each preliminarily fitted by a superposition of given functions” because it is unclear what mean “a linear combination” and “a superposition of given functions”.

What kind of functions can be considered as “given functions”? Please clarify.

13. Claim 59 is rejected as vague and indefinite in view of phrase “determining that a known melting curve data set with a least statistical error is defined as the sequence information of the sample single-stranded DNA fragment” because it is unclear what it intended. For example, how a known melting curve data set with a least statistical error can be defined as the sequence information of the sample single-stranded DNA fragment. Does the phrase “a known melting curve data set with a least statistical error” mean a known melting curve data set with least statistical error? It was known that a melting curve is correlated with heat denaturation of nucleic acid and is not correlated with the sequence information of a nucleic acid. Please clarify.

Conclusion

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG

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94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
September 20, 2002



ETHAN C. WHISENANT
PRIMARY EXAMINER